REMARKS

Claims 17-19, 21-24, 26, 29 and 42-44 are pending and under consideration in the present application.

Applicants acknowledge the Examiner's withdrawal of claims 25, 30 and 31 from consideration as being drawn to the non-elected invention.

Rejection of claims 17-19, 21, 26, 29 and 42-44 under 35 U.S.C. § 102(b)

Claims 17-19, 21, 26, 29 and 42-44 were rejected under 35 U.S.C. § 102(b) as being anticipated by Ish-Horowicz et al. (U.S. Patent No. 5,004,924; hereinafter "Ish-Horowicz"). Applicants respectfully disagree for the following reasons.

The text of 35 U.S.C. § 102(b) sets forth that:

> A person shall be entitled to a patent unless the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The Ish-Horowicz patent, however, was not published more than one year prior to the earliest priority date of the present invention. The Ish-Horowicz patent issued on December 21, 1999. However, the earliest priority date of the present application is May 31, 1996. Therefore, Ish-Horowicz cannot anticipate the present invention because Ish-Horowicz was not "patented or described in a printed publication in this or a foreign country more than one year prior to the date of application for patent in the United States." Reconsideration and withdrawal of the Examiner's rejection of claims 17-19, 21, 26, 29 and 42-44 pursuant to 35 U.S.C. § 102(b) is respectfully requested.

Rejection of claims 17 and 22-24 under 35 U.S.C. § 103(a)

Claims 17 and 22-24 were rejected under 35 U.S.C. § 103(a) as being anticipated by Ish-Horowicz, further in view of Ellison et al. (J. Biol. Chem. (1991) 266:21150-21157; Hereinafter, "Ellison"). It is the Examiner's view that because Ish-Horowicz discloses an isolated nucleic acid encoding a polypeptide with 99.7% sequence homology to a claimed polypeptide of the present invention, and because Ellison teaches various tagged polypeptides, that the combination of reference renders obvious Applicants' presently claimed invention. Applicants respectfully disagree, and traverse the rejection for the following reasons.

The arguments set forth above in response to the Examiner's rejection under 35 U.S.C. § 102(b), based on Ish-Horowicz, apply with equal force in response to the Examiner's obviousness rejection. That is, Ish-Horowicz cannot be used as an anticipatory reference against presently-claimed invention, because Ish-Horowicz was not "patented or described in a printed publication in this or a foreign country more than one year prior to the date of application for patent in the United States." Furthermore, combination of Ish-Horowicz with the Ellison reference does not correct this deficiency.

Nonetheless, assuming, *arguendo*, that the Examiner maintains the rejection based on Ish-Horowicz in view of Ellison, Applicants respectfully traverse this rejection, and respectfully submit that Ish-Horowicz, in view of Ellison, does not render claims 17 and 22-24 *prima facie* obvious under 35 U.S.C. § 103(a) for the following reasons.

The three-prong test which must be met for a reference or a combination of references to establish a *prima facie* case of obviousness has not been satisfied in the instant matter. The MPEP states, in relevant part:

> To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all of the claim limitations. MPEP § 2142.

None of these criteria have been met here, and therefore, Applicants respectfully submit that the Examiner has not met her burden with respect to the establishment of a *prima facie* case of obviousness.

The present application claims "An isolated polypeptide encoded by the nucleic acid sequence comprising the sequence from nucleotide number 1 to nucleotide number 3201 of SEQ ID NO:2." Applicants respectfully remind the Examiner that the transitional term "comprising", which is synonymous with "including," "containing," or "characterized by," has been defined by the courts to mean that the named elements are essential, but other elements may be added and still form a construct within the scope of the claim. *Moleculon Research Corp. v. CBS, Inc.*, 793 F.2d 1261, 229 USPQ 805 (Fed. Cir. 1986); *In re Baxter*, 656 F.2d 679, 210 USPQ 795 (CCPA 1981). As applied to claims 17 and 22-24, this means that the

claimed nucleic acid sequence contains at least nucleotide number 1 to nucleotide number 3201 of SEQ ID NO:2, and may contain additional nucleotides.

Neither Ish-Horowicz nor Ellison teach or disclose a nucleic acid sequence containing at least "nucleotide number 1 to nucleotide number 3201 of SEQ ID NO:2." That is, neither Ish-Horowicz nor Ellison teach a nucleic acid sequence that is "100%" identical to a nucleic acid sequence containing nucleotide number 1 to nucleotide number 3201 of SEQ ID NO:2. While the Examiner does not provide a specific level of percent identity between the nucleic acid disclosed by Ish-Horowicz and that claimed by Applicants (e.g., nucleotide number 1 to nucleotide number 3201 of SEQ ID NO:2), the nucleic acid of Ish-Horowicz that encodes a polypeptide which is "99.7%" identical to the polypeptide encoded by Applicant's nucleic acid is necessarily less than 100% identical. Furthermore, neither Ish-Horowicz nor Ellison provide any teaching or suggestion as to how one of skill in the art would arrive at Applicants' presently-claimed invention. Therefore, neither Ish-Horowicz nor Ellison provide any suggestion or motivation to arrive at the presently-claimed invention.

The partial nucleic acid sequences disclosed by Ish-Horowicz do not lead the skilled artisan to Applicants' presently-claimed invention. The partial nucleic acid sequences taught by Ish-Horowicz differ from the presently-claimed nucleic acid sequence containing "at least nucleotide number 1 to nucleotide number 3201 of SEQ ID NO:2." In an unpredictable art such as that involving the identification of nucleic acid sequences, the disclosure of a single nucleic acid sequence encoding a polypeptide that differs from what is presently claimed by Applicants can amount to nothing more than an invitation to experiment. This is because Applicants' presently-claimed nucleic acid sequence containing "at least nucleotide number 1 to nucleotide number 3201 of SEQ ID NO:2" was disclosed *for the first time* in the present application.

Further, Ish-Horowicz is not an enabling reference with respect to Applicants' presently-claimed invention. The skilled artisan would necessarily need to conduct "undue" experimentation in order to arrive at Applicants' claimed invention. Prior to the present invention, the skilled artisan would have had no more than a mere wish or hope to arrive at the previously-unknown sequence of a nucleic acid encoding a polypeptide encoded by Applicants' claimed sequence containing nucleotide number 1 to nucleotide number 3201 of SEQ ID NO:2. Applicants direct the Examiner's attention to the reference by Ng et al., attached herewith

(Genome Res. (2001) 11: 863-874). Ng et al. discusses how every potential amino acid mutation in a protein may affect protein structure and/or function. Even the computational tools used by Ng et al. are not fully or consistently accurately predictive of the effect of the mutation of any given amino acid at any given position in a protein.

The Ellison reference does not cure this deficiency, as Ellison teaches only the protein "ubiquitin," which is not even related to Jagged or Notch proteins. Moreover, there is no teaching or suggestion in Ellison of the nucleic acid residues that must be changed in the Ish-Horowicz sequence in order to arrive at Applicants' claimed sequence. Furthermore, there is no teaching or suggestion in Ellison of the *identity* of the nucleic acid residues to which the unknown, yet specific nucleic acid residues must be changed in the Ish-Horowicz sequence in order to arrive at Applicants' claimed sequence.

Because neither Ish-Horowicz nor Ellison discloses Applicants' presently-claimed sequence, and because neither reference provides any motivation or suggestion to arrive at Applicants' presently-claimed sequence, Ish-Horowicz and Ellison, when taken together, do not provide any suggestion or motivation to the skilled artisan to arrive at Applicants' presently-claimed invention. Furthermore, because Ish-Horowicz and Ellison, when taken together, do not provide any suggestion or motivation to the skilled artisan to arrive at Applicants' presently-claimed invention, the skilled artisan would not have any reasonable expectation of success in arriving at the invention set forth in claims 17 and 22-24.

For the reasons discussed above, the combination of Ish-Horowicz and Ellison does not render claims 17 and 22-24 *prima facie* obvious under 35 U.S.C. § 103(a) and, therefore, the rejection should be reconsidered and withdrawn.

Summary

Applicants respectfully submit that the arguments set forth herein evidence that the pending claims are in full condition for allowance. Accordingly, favorable examination of the claims is respectfully requested at the earliest possible time.

Respectfully submitted,

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Date

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